

April 29, 2019

Julian Leichty
Office of Environmental Health Hazard Assessment
Proposition 65 Implementation
P.O. Box 4010, MS-12B
Sacramento, California 95812-4010

RE: Request for relevant information on the reproductive toxicity (developmental toxicity endpoint) of Cannabis and Cannabis-related chemicals

Dear Mr. Leichty,

The following comments are submitted by the American Herbal Products Association (AHPA), the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters and distributors of herbs and herbal products.

AHPA has prepared these comments in response to the March 15, 2019 request from OEHHA titled "Request for relevant information on the reproductive toxicity (developmental toxicity endpoint) of Cannabis and Cannabis-related chemicals." In this request, OEHHA indicates that it has identified the following chemicals for review by the Developmental and Reproductive Toxicant Identification Committee (DARTIC) of OEHHA's Science Advisory Board as possible reproductive toxicants under Proposition 65:

Cannabis (marijuana)
Marijuana (cannabis) smoke
Cannabis extracts
Δ-9-tetrahydrocannabinol (THC)

AHPA's members are engaged in the commerce of herbs and herbal products. In the course of this commerce many plant species are traded as bulk commodities, as plant extracts and finished products such as teas and dietary supplements, or as ingredients in such extracts and products, and may include cultivars of *Cannabis sativa* (including those that are classified as hemp<sup>1</sup>). AHPA's members therefore have an interest in the subject of the March 15<sup>th</sup> request described here insofar as that request relates to this plant species and various products derived from it that are legal under federal law as excluded from the definition of "marihuana," or are legal under

<sup>&</sup>lt;sup>1</sup> As established by the 2018 Farm Bill amendments to the Agricultural Marketing Act of 1946 (section 297A), "The term 'hemp' means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

<sup>&</sup>lt;sup>2</sup> 21 U.S.C. § 802 (16).

State law in a State that allows such products to be cultivated, processed, sold, possessed and used.

AHPA recommends that DARTIC's review of scientific data regarding these cannabis articles consider the following issues:

- Any eventual classifications of these articles under Proposition 65 should be specific to the route of consumption of the substance under study, and the data used to support any eventual classification must be specific to that route of consumption. For example, if DARTIC evaluates scientific studies that consider or draw conclusions on the effects of smoking marijuana on male or female reproduction, those publications should not be considered relevant to an evaluation of the effects of oral consumption of any cannabis ingredients.
- Publications that consider or draw conclusions on the effect of isolated compounds, and in particular on  $\Delta$ -9-tetrahydrocannabinol (THC), should not be extrapolated to make any conclusion on any other isolated cannabis compound, or any cannabis ingredients that contain little to no THC.
- The scientific basis for any classification decision should be limited to reproductive toxicity studies on specific parts of the *Cannabis* plant, so that studies on the effects of oral consumption of the leaf or flower should not be extrapolated to the seed or other parts of the plant, or to other products like fiber or seed oil.

In summary, AHPA strongly recommends that OEHHA ensures that its communications to DARTIC envision possible outcomes for cannabis articles sufficiently differentiated by the part of the cannabis plant identified in the scientific references and the route of exposure, for example, "cannabis (exclusive of seed, seed oil or fiber) smoke for inhalation;" or "cannabis flower extract for inhalation."

AHPA greatly appreciates the opportunity to present comments during this OEHHA information request process. We welcome any questions that may arise from AHPA's comments and look forward to reviewing the hazard identification materials once published by OEHHA.

Respectfully submitted,

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